**These are some of the questions and comments that were received electronically prior to the public workshop**

## DG-1145 Development Questions

C.I.10-1 It appears that all the information required by this section of the guidance is included in the generic design control document (DCD) for a combined license (COL) application referencing the AP1000 certified design with the exception of the circulating water system design, and the program descriptions required by COL information and actions items identified by final safety evaluation report (FSER) for Chapter 10. Does the Staff agree with this assessment?

C.I.10-2 It is difficult to compare this guidance and the requirements of the SRP for Chapter 10. Can you identify any significant differences between these two documents?

C.I.10-3 The criteria listed in the middle of page 10 ("Demonstrate consistency with the requirements of GDC 5, 44, 45 -----") appear to apply to more than just section C.I.10.4.7. Is this just a formatting issue, i.e., do these apply to sections C.I.10.4.1 through 7?

C.I.10.2.3.3-1 A general comment is that some guidance on the timing for providing information would be very helpful. For example, section C.I.10.2.3.3 asks for a description of the pre-service inspection procedures and acceptance criteria for turbine rotors. It is expected that the combined license (COL) application would contain a general description and reference any applicable standards with the information available at the time of the application. The procedures and acceptance criteria would probably be finalized during construction and be available for NRC inspection. Does that meet the expectation of section C.I.10.2.3.3?

C.I.13-1 Experience with applications currently being developed is that it would be more efficient to locate organization and staffing requirements for other plant organizations such as Radiation Protection and Fire Protection in Chapter 13 rather than in the program description sections of the SAR (e.g., 12.5 and 9.5.1). Is this an acceptable alternative to the guidance provided in the current draft of DG-1145?

C.I.13.1.1.1-1 Item 2 in Section 13.1.1.1 requires a combined license (COL) applicant to provide a description of the development and implementation of staff recruiting programs. This information should not be required if the application adequately describes the position requirements and numbers of individuals needed to staff the plant and supporting organizations. What is reason behind and the regulatory basis for this proposed guidance?

C.I.13.1.1.3-1 Section 13.1.1.3 requires that resumes be provided for assigned persons identified in section 13.1.1.2. The section also requires that the qualification requirements for those positions be identified. Many current operating plants have removed resumes from the SAR because of the administrative burden associated with updating those sections to reflect personnel changes resulting from rotations, reorganizations, retirements, etc. The detailed qualification requirements for key positions are licensee commitments and must be met or alternatives justified as these positions are filled. At the time a combined license (COL) application is filed, the requirements for these positions can be identified in accordance with regulatory guidance, such as Regulatory Guide 1.8, but many of the positions may not be filled. It is recommended that the requirement for resumes be removed since the position qualification requirements will allow the staff to assess organization qualification adequacy. The qualifications of individuals filling those positions can be assessed through inspections at the sites after the application is filed. This same issue exists for plant operating personnel in section 13.1.3.2.

C.I.13.1.2-1 Item 3 in Section 13.1.12, requires a commitment to meet the applicable requirements for a Fire Protection Program. Those commitments are also located in Section 9.5.1. This item seems out of place for Chapter 13.

C.I.13.1.2.1-1 Section 13.1.2.1 requires an applicant to provide an organization chart showing the title of each position, the number of persons assigned common or duplicate positions, number of operating shift crews, etc. It is anticipated that this level of detail may not be known at the time the combined license (COL) application is submitted. A high level organization chart could be prepared and submitted in the application with more detail developed later and made available for inspection. The guidance should be modified to indicate that this information will be developed after the application is submitted. This position is consistent with SRP 13.1.2-13.1.3, Rev. 5 issued July 2005

C.I.13.2-1 The industry believes that Section 13.2 should be written as a either a generic or standardized combined licenses (COL) application section. Please identify any concerns that the NRC may have with the industry taking this approach.

C.I.13.2-2 Throughout Section 13.2, NRC refers to "titles of positions". To facilitate standardization of Section 13.2, does the NRC staff agree that it would be acceptable to provide "functional position descriptions" whenever the phrase "titles of positions" is used? This would allow development of a generic section without making applicant specific title distinctions that will be inconsistent from utility to utility.

C.I.13.2-3 Throughout this section 13.2, NRC refers a number of formal instruction techniques including "classroom instruction" and "lecture". Does the NRC staff agree with use of the term "formal instruction" to encompass classroom instruction, lecture and other formal instruction techniques like e-learning applications to avoid limitation in delivery techniques?

C.I.13.2-4 In Section 13.2, the NRC refers to the development of "contingency plans" in the event of delays in fuel loading. The industry believes that implementation of re-qualification or retraining programs suffice for the contingency plans requested. Does the NRC staff agree? If not, why?

C.I.13.2.1.1-1 Item 4 in Section 13.2.1.1 identifies Regularoty Guide 1.149 along with several other regulations and refers to all of them as "requirements." The NRC Regulatory Guide is only guidance, not a requirement. Does the NRC staff agree that DG-1145 should be revised to reflect the distinction between the requirements and guidance?

C.I.13.2.1.1-2 Item 6 in Section 13.2.1.1 discusses implementation milestones. Does the NRC staff agree that these milestones could be identified relative to fuel load as opposed to calendar dates?

C.I.13.2.1.1-3 Item 2 in Section 13.2.1.1 indicates that the application should include "a commitment to meet the requirements of 10 CFR 50.120 at least 18 months before fuel load." As this is a regulation that must be met, why is it necessary to include a commitment in the final safety analysis report (FSAR)?

C.I.13.2.1.1-4 Item 3 in Section 13.2.1.1, please identify the training programs that they envision including in this section

C.I.13.2.1.1-5 Item 3 in Section 13.2.1.1, the industry proposes to write a description of the systems approach to training (SAT) process to address the elements of this process that will provide assurance that operation and plant staff are trained to perform difficult, important, and infrequently required tasks as well as those required by regulation. This will include:

- Analyze Training Needs , starting with Job Task Analysis,
- Design training programs and training courses to address task objectives and the skills and knowledge needed,
- Develop training content, presentation, and learning techniques, and
- Evaluations to ensure that the learner retains sufficient knowledge and skills to perform the tasks as well as measuring and monitoring training effectiveness.

Please identify any concerns that the NRC may have with this approach.

C.I.13.2.1.1-6 Item 3 in Section 13.2.1.1, please clarify the level of detail expected in the "subject matter of each course"? Does the NRC staff agree that it is sufficient to identify "proposed topics" instead of "syllabus" as this will be consistent with other portions of this chapter?

C.I.13.2.1.1-7 Item 3 in Section 13.2.1.1 indicates that training programs for three different levels of prior staff experience be detailed. As all programs will be designed for

an individual without prior training, qualification or experience, does the NRC staff agree that a description of the systems approach to training as described above would be adequate to address this issue?

C.I.13.2.1.1-8 Item 3 in Section 13.2.1.1 indicates that the application should include "a commitment to conduct an onsite formal training program and on-the-job training such that the entire plant staff will be qualified before the initial fuel loading." Industry believes that there is no requirement, or need, to have the entire plant staff qualified before fuel load. Such a condition will rarely occur over the lifetime of the plant due to continuous hiring of new personnel. The new personnel become a part of the plant staff immediately but often require some period of time to become "qualified." It is necessary only to have a sufficient number of qualified plant staff to operate the plant. Does the NRC staff agree that it would be appropriate in DG-11454 to replace the phrase "the entire plant staff" with the phrase "sufficient plant staff to ensure safe plant operations"?

C.I.13.2.1.1-9 Item 4 point e in Section 13.2.1.1 includes the sentence "The program description is verified to include the course of instruction, the number of hours of each course and the organization conducting the training." Why is this sentence included in subpoint e as opposed to being included after the final sentence of Item 4? It would be more consistent with the Regulatory Guide if it was included with the final sentence of the item.

C.I.13.2.1.1-10 The last sentence of item 4 in Section 13.2.1.1 indicates a commitment to verify that initial fire protection training be completed prior to receipt of fuel. This is not consistent with fire protection program implementation guidance schedule (currently in 13.4). Please identify any concerns that the NRC may have with the industry taking this phased approach.

C.I.13.2.1.1-11 Section 13.2.1.1 - Item 5- As a job task analysis is an element of the systems approach to training, as described in the question for item 3 in this section. Industry proposes using the description of a systems approach to training to address this issue. Please identify any concerns that the NRC may have with the industry taking this approach.

C.I.13.2.1.1-12 Item 6 in Section 13.2.1, please clarify whether this item refers to a program description or a course description.

C.I.13.2.1.1-13 Section 13.2.1.1 - Item 7-Industry believes that the separate emergency planning section addresses this item. Please identify any concerns NRC may have with this approach.

C.I.13.2.1.1-14 Section 13.2.1.1 - Item 7-Please clarify this item. The first sentence refers to radiological emergencies and the second sentence and sub-points a and b don't seem to be related.

C.I.13.2.2.1-1 Item 3 in Section 13.2.2.1, NRC uses the phrase "should include the content

described in 10 CFR 55.59 or should be based on the use of a systems approach to training (SAT)". Why is the use of a systems approach to training not included in this section as it refers to the same re-qualification program?

C.I.13.2.2.3-1 Section 13.2.2.3 discusses replacement training. Industry believes that all replacement personnel would be required to go through initial training to become qualified and re-qualification training to maintain their qualification. Please identify any concerns NRC may have with using an approach that includes initial and re-qualification only, why is there a separate section on replacement training?

C.I.13.4-1 Based on the proposed content, it is suggested that this section should be titled "Operational Program Implementation.

C.I.13.4-2 The scope of this section was discussed in Workshop 2 under DG-1145, Section C.IV.4. It is anticipated by industry that resolution of comments presented for that section may result in some corresponding changes to this section.

C.I.16-1 A combined license (COL) application final safety analysis report (FSAR) Chapter 16 must include the proposed Technical Specifications and Bases in accordance with 10CFR 50.36, 50.36a, and 52.79. This draft guidance requires, in addition, that an application describe the procedures and controls for preparation of Technical Specifications and processing Technical Specification changes. This information is not required by 10 CFR 52 as part of the application except the general requirement to discuss administrative controls of processes. Current rules (10 CFR 50.59, 50.90, DCR VIII.C) provide very specific requirements for license amendments and departures from generic technical specifications. The description of (1) "procedures … for developing the technical specifications"; (2) "controls used to prepare risk information"; and (3) administrative controls to assure future license amendments comply with the regulations are details that are not considered appropriate for a COL application. Internal processes and procedures that ultimately result in submittal of an application (initial or for future amendment) are more appropriately the subject of inspections during construction and operation. Particularly, in the case of future license amendment requests (including future Technical Specification change requests), where the regulatory requirements are clear and well understood, expecting descriptions of compliance processes several years in advance of their use should not be required in the COL application or any docketed correspondence.

C.I.16-2 This guidance section implies that use of Regulatory Guide 1.177 to support "technical specification changes" is a requirement. There is no current regulatory requirement to risk-inform technical specifications. Regulatory Guide 1.177 provides an optional process for risk-informing Technical Specification changes and the status of this Regulatory Guide should remain consistent with other NRC guidance. The language in this section should indicate that it is

optional consistent with Regulatory Guide 1.177.

C.I.16-3 A statement is made in the first paragraph on page 1 of 4 that a combined license (COL) should include technical specifications and associated bases "conforming to the approved generic technical specifications for the certified design (if applicable) and consistent with the standard technical specifications in NUREG-1430 through 1434 , as appropriate, with appropriate site-specific deviations." Paragraph 3 of page 1 of 4 states that "Justification should be provided for deviations from the certified design generic or standard technical specifications ------". Development of the generic technical specifications for the currently certified designs included evaluation against the standard technical specifications for the applicable reactor vendor. DCRs require the site-specific technical specifications to be developed with specific deviations from the generic design control document (DCD) technical specifications justified by exemption requests. A separate justification of the differences from the standard technical specifications would not make sense. In the case of an application made without referencing a certified design, it may be appropriate to present comparative information against some other approved standard Technical Specifications, however, the appropriate standard could be a prior certified design or NUREG-1430 through 1434. Please confirm that this is the intent of these two paragraphs.

C.I.16-4 In general, the guidance is not clear on different processes and expectations for applications that do or do not reference a certified design. It appears that some portions may be addressing one situation while other portions address the other. As such, clear guidance is not achieved. This appears to present the same problem as we have discussed with previous draft guidance sections.

C.I.17.4-1 The COL DRAP for an application referencing a certified design will consist of the generic DCD DRAP and the COL scope DRAP. Since the generic DCDs include the bulk of the information for the plant design, the COL scope should be much smaller and focus on the design scope outside the certified design. Does the Staff agree, for this case, that the COL application should reference the applicable generic DCD and add specific information related to the applicant scope design? Of course, the DRAP for the entire plant scope would be the responsibility of the COL holder.

C.I.17.4-2 In general, the guidance is written similar to an SRP with direction for the Staff to review certain material in an application. Directing the guidance to the applicants would make it more clear what is expected in an application versus the information maintained outside the FSAR that the NRC staff may audit.

C.I.17.4.1-1 Section I.17.4.1 states that a combined license (COL) applicant is responsible for developing and implementing an operational reliability assurance process (ORAP). This statement is inconsistent with the Staff's response to the Commission SRM for SECY 94-084 as indicated in SECY 95-132, Attachment 2.

In those documents, the staff agreed that the objectives of a stand-alone ORAP could be accomplished through implementation of existing regulatory requirements such as the Maintenance Rule, 10 CFR 50.65, and 10 CFR 50, Appendix B, quality assurance (QA) Program. The requirement to "develop and implement" an ORAP seems to be inconsistent with the Commission direction and previous staff guidance.

C.I.17.5-1 The industry made a number of significant comments on SRP Section 17.5. The industry has similar concerns about Section 17.5 of DG-1145. See NEI letter dated April 11, 2006.

C.I.17.5-2 The level of detail that is being proposed for this Section of DG-1145 is normally covered in utility implementing procedures. If this level of detail needs to be in the combined license (COL) application there won't be a need for implementing procedures. The industry would expect to have program level information in the COL application. Utilities are typically reference Standards that they commit to in the quality assurance program document (QAPD) and does not discuss the details contained in the standards in the QAPD. The details of implementation are typically left to implementing procedures.

C.I.17.5-3 Section 17.5 does not clearly delineate between construction and operational requirements.

C.I.17.5-4 The first paragraph of 17.5.2 implies that a quality assurance program document (QAPD) submitted for both construction and operational phases must be in accordance with SRP 17.5. However, most COL applicants already have existing nuclear plants with their quality assurance program documents QAPDs approved under SRP Section 17.3 The Note on 17.5.1 indicates that SRP 17.5 will be used by NRC reviewers not Sections 17.1, 17.2, and 17.3. In light of the above, is the NRC saying that if you have an existing SRP Section 17.3 based on self assessment and performance based assessments, that it can't be used during the operational phase. Current QAPDs are already approved by the NRC and it wouldn't make any sense to have two different QA Programs in the same fleet of plants. Utilities have typically tried to have common program within a fleet of plants. Please clarify.

C.I.17.5.1-1 In Section 17.5.1 on page 7, provisions are made for an applicant to propose and justify using the existing quality assurance (QA) program for its operating "fleet." What is the process for using the existing "fleet" QA program? Are exceptions required to the bases documents of SRP 17.5, since many existing programs are based on earlier guides and standards?

C.I.17.5.1-2 Section 17.5.1 on page 7, a statement is made that an applicant should incorporate the most recently NRC-endorsed standard. For those utilities developing a quality assurance program document (QAPD) based on NQA-1-1994, can provisions be made to accept this standard even though a later version may be endorsed by the time a combined license (COL) application

is submitted? Related to this, does the NRC envision issuing new versions of RG 1.28 and RG 1.33 endorsing later versions of NQA-1 and ANS-3.2?

C.I.17.5.1-3 On page 8 in Section 17.5.1, a requirement is imposed to address planned sharing of personnel for stations that incorporate, or plan to incorporate, other nuclear or non-nuclear power generating facilities. Any planned sharing of personnel would be pure speculation at the time the combined license (COL) application is submitted. This level of detail is not necessary to implementing the QA program or programs at a respective station.

C.I.17.5.1.1-1 In regards to Section 17.5.1.1 on page 8, during the last thirty years there have been a number of items that have been eliminated through NRC and utility review and are not performed in current quality assurance (QA) programs. Items 4 and 8 (in line reviews) are examples of this. The NRC should eliminate items in this section that they have reviewed and approved for utilities to reduce their QA Program commitments.

C.I.17.5.3-1 The Second bullet in section 17.5.3 suggests that the utility provide and maintain a complete list of structures, systems, and components (SSCs). Industry uses drawings and other means to accomplish this same function. This should be written such that the utility will describe the method to identify SSCs to which the program applies.

C.I.17.5.3-2 In regards to Bullet 4 in Section 17.5.3.F, quality assurance (QA) review and concurrence on procedures has been removed from current QA programs under approved NRC safety evaluation reports (SERs). Bullet 5 in section 17.5.3.F describes periodic procedure reviews. This level of detail is similar to comments in item 2. Bullet 7 should be sufficient to address procedure review and feedback for improvement of procedures.

C.17.5.3-3 Section 17.5.3.Y seems to imply that a utility would put non safety related structures, systems, and components (SSCs) into their quality assurance (QA) program. This is not required in current operating plant QA Programs. (Note: Unlike draft SRP 17.5.Y.1, DG-1145 does not make the distinction between applicants for passive advanced light water reactor designs or COL holders that choose to implement 10 CFR 50.69, and the other applicants.)

C.I.17.5.3-4 There is very little guidance in section 17.5.3.Y. It is not married well to the SECY 94-084 and 95-0132 regulatory treatment of non-safety systems (RTNSS) guidance and it should be.

C.I.17.5.3-5 In Section 17.5.3.Y there is no explicit mention of "availability controls." The expectation was that this section would provide us with the answer as to where we put regulatory treatment of non-safety systems (RTNSS) Availability Controls. Currently D-RAP, operational reliability assurance process (O-RAP), and Maintenance Rule are part of 17.4 and 17.6. RTNSS controls can make sense

here. (Although in AP1000 they are in Table 16.3-1) Recommend the actual "Specs" as an Appendix to Chapter 17, or IBRef within 17.4 to an external document (e.g., current fleet "TRM" like document).

C.I.17.5.3-6 Section 17.5.3.Z is not clear. Does this mean Nuclear Safety Review Board, Independent Safety Engineering Group (ISEG), etc. Additionally, some utilities have eliminated this requirement in their quality assurance (QA) Program. This was achieved through NRC reviews and safety evaluation reports (SERs). Are we locked into the DG-1145 independent review process or can we use an existing approved process?

C.I.17.6-1 Does Section 17.6 imply that the maintenance rule systems are scoped into the quality assurance (QA) Program.

C.I.17.6-2 It is not clear exactly what needs to be in the combined license (COL) applicatoin and what can simply be in the quality assurance program document (QAPD).

C.I.17.6-3 This section of the draft guidance provides a comprehensive listing of everything that is required to implement a Maintenance Rule Program. In fact, there are some items, e.g., qualification and training, that are beyond the scope of the maintenance rule. The section does not provide guidance for what should be included in a combined license (COL) application versus the information maintained outside the final safety analysis report (FSAR) that the NRC staff may audit.

C.I.17.6-4 Some of the information required by this section will not be available at the time the combined license (COL) is prepared. The guidance should reflect that some maintenacne rule program information will be developed post COL application and will be maintained outside the final safety analysis report (FSAR).